



09-02-03

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VPI/00-08

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : L. Helms
Group Art Unit : 1615
Applicants : Bhami Shenoy et al.
Application No. : 10/034,950 Confirmation No.: 9344
Filed : December 26, 2001
For : CRYSTALS OF WHOLE ANTIBODIES AND
FRAGMENTS THEREOF AND METHODS FOR
MAKING AND USING THEM

New York, New York
August 29, 2003

Hon. Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER FOR
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

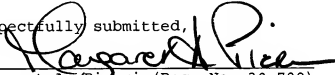
Transmitted herewith is a Supplemental Information Disclosure Statement in the above-identified application. This Statement is being submitted more than three months from the application filing date but before the mailing of a first Office Action on the merits under 37 C.F.R. § 1.97(b)(3), or a notice of allowance under 37 C.F.R. § 1.311, therefore it is timely without the payment of any additional fees.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINKED THROUGH. /AK/

Express Mail No.

The Director is hereby authorized to charge payment of any additional fees required in connection with the accompanying Supplemental Information Disclosure Statement, or credit any overpayment, to Deposit Account No. 06-1075. A duplicate copy of this transmittal letter is transmitted herewith.

Respectfully submitted,



Margaret A. Pierri (Reg. No. 30,709)
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Andrew K. Holmes (Reg. No. 51,813)
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SUPPLEMENTAL STATEMENT UNDER
37 C.F.R. § 1.56 AND § 1.97(b)

Sir:

This Statement supplements applicants' Information
Disclosure Statement, dated June 27, 2003.

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), applicants,
through their attorneys, make of record the following documents:

Express Mail No.
#K 708051245 US

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AK/

OTHER DOCUMENTS

Baselga et al., "Recombinant Humanized Anti-HER2 Antibody (Herceptin™) Enhances the Antitumor Activity of Paclitaxel and Doxorubicin against HER2/neu Overexpressing Human Breast Cancer Xenografts," Cancer Research, Volume 58, pp. 2825-2831 (1998).

Brange et al., "Insulin Analogs With Improved Pharmacokinetic Profiles," Advanced Drug Delivery Reviews, Volume 35, pp. 307-335 (1999).

Colbern et al., "Antitumor Activity of Herceptin in Combination with STEALTH Liposomal Cisplatin or Nonliposomal in a HER2 Positive Human Breast Cancer Model," Journal of Inorganic Biochemistry, Volume 77, pp. 117-120 (1999).

Flieger et al., "Mechanism of Cytotoxicity Induced by Chimeric Mouse Human Monoclonal Antibody IDEC-C2B8 in CD-20-Expressing Lymphoma Cell Lines," Cellular Immunology, Volume 204, pp. 55-63 (2000).

Ghetie et al., "FcRn: the MHC Class I-related Receptor That is More Than an IgG Transporter," Immunology Today, Volume 18, pp. 592-598 (1997).

Hainsworth, "Rituximab as First-Line and Maintenance Therapy for Patients With Indolent Non-Hodgkin's Lymphoma: Interim Follow-Up of a Multicenter Phase II Trial," Seminars in Oncology, Volume 29, pp. 25-29 (2002).

Harris et al., "Comparison of Intact Antibody Structures and the Implications for Effector Function," Advances in Immunology, Volume 72, pp. 191-205 (1999).

Jen et al., "Diamonds in the Rough: Protein Crystals from a Formulation Perspective," Pharmaceutical Research, Volume 18, pp. 1483-1488 (2001).

Keating et al., "Infliximab, An Updated Review of its Use in Crohn's Disease and Rheumatoid Arthritis," Adis Drug Evaluation, Volume 16, pp. 111-148 (2002).

Kuznetsov et al., "Chimeric Human-Simian Anti-CD4 Antibodies form Crystalline High Symmetry Particles," Journal of Structural Biology, Volume 131, pp. 108-115 (2000).

Leyland-Jones et al., "Role of Herceptin® in Primary Breast Cancer: Views from North America and Europe," Oncology, Volume 61, pp. 83-91 (2001).

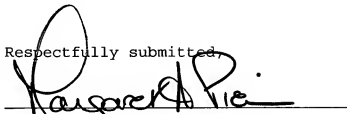
Ma et al., "Carbohydrate Analysis of a Chimeric Recombinant Monoclonal Antibody by Capillary Electrophoresis with Laser-Induced Fluorescence Detection," Anal. Chem., Volume 71, pp. 5185-5192 (1999).

Applicants have attached a PTO-1449 Form listing these documents. Applicants request that these documents: (1) be fully considered by the Examiner during examination of this application and (2) be printed on any patent that may issue from this application. Applicants are submitting this Statement before the issuance of a first Office Action on the merits under 37 C.F.R. §1.97(b) (3).

The Director is hereby authorized to charge payment of any fees required in connection with this Supplemental Information Disclosure Statement to Deposit Account No. 06-1075.

A duplicate copy of the accompanying transmittal letter including that authorization is transmitted herewith.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Margaret A. Pierri", is written over a horizontal line.

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